TEV-TROPIN® Offers:

Growth Solutions

Support Services
for your Pediatric Patients

TEV-TROPIN®
[somatropin (rDNA origin) for injection]

CAN DO!

Common Questions About Growth Solutions®

General Procedures

Q: What kind of support and guidance does Growth Solutions® provide for patients with growth hormone deficiency (GHD)?

A: Specially trained nurses can walk patients and their caregivers through the reconstitution and administration processes. They can also answer questions.

A Growth Solutions® Benefits Investigation Specialist can provide ongoing assistance related to insurance changes and recertification.

Q: How does a patient become enrolled in the Growth Solutions® program?

A: Once a patient is diagnosed with GHD and prescribed TEV-TROPIN®, the physician or office staff can submit an enrollment form, which includes a prescription. This form is available on our website, www.tev-tropin.com, and can be submitted via fax to 877-TEV-TROP (877-838-8767). In addition, a patient can be enrolled directly by calling the toll-free Growth Solutions® number 866-TEV-TROP (866-838-8767).

Q: How do my patients and my staff contact Growth Solutions®?

A: There are 3 convenient options for contacting Growth Solutions®:

- Call 866-TEV-TROP (866-838-8767). We have a trained staff of registered nurses and Benefits Investigation Specialists available for direct consultation from 8:00 AM to 8:00 PM Central* time (Monday through Friday).

*9 AM to 9 PM Eastern; 7 AM to 7 PM Mountain; or 6 AM to 6 PM Pacific.

- Fax enrollment forms and other requests to 877-TEV-TROP (877-838-8767).
- Visit www.tev-tropin.com and click on the link for Growth Solutions®. You'll find administration support information online, as well as helpful links to other online resources about growth hormone therapy.

Educational and Support Materials

Q: When should my patients expect their welcome call and free Welcome Backpack Kit?

A: A registered nurse from Growth Solutions® will call each patient's parents or caregivers promptly following initial enrollment. The Welcome Backpack Kit, including patient materials, is sent to the patient and usually arrives around the same time as the first shipment of TEV-TROPIN®.

Q: Is an injection device available from Growth Solutions®?

A: Yes. We provide a free Inject-Ease® to patients upon request. Inject-Ease® hides the needle and can help make injections easier. Interested patients should simply contact Growth Solutions®.

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Common Questions About Growth Solutions®

Step-by-step through the Growth Solutions® process

1. Physician diagnoses GHD and prescribes TEV-TROPIN®
2. Nurse or office staff submits enrollment form via fax to Growth Solutions®: 877-TEV-TROP (877-838-8767)
3. Patient receives welcome call from Growth Solutions® to review the process of getting therapy started
4. Growth Solutions® begins benefits investigation process:
   - Identifies insurance coverage and patient co-pays
   - Promptly works through the insurance authorization process
   - Seeks alternate source of coverage (if necessary)
5. Growth Solutions® updates physician via fax when an enrollment form has been received and when coverage has been identified
6. Growth Solutions® sends out a *free* Welcome Backpack Kit to help you initiate treatment with TEV-TROPIN®
7. Home health agency or nurse educator contacts the parent/caregiver to arrange complimentary training appointment (if needed)
8. Growth Solutions® identifies specialty pharmacies where patient can have TEV-TROPIN® prescriptions filled, including home delivery when available
9. Growth Solutions® monitors insurance coverage continuously to avoid interruptions in therapy

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Benefits Investigation

Q: What kind of reimbursement support does Growth Solutions® offer?

A: Growth Solutions® has Benefits Investigation Specialists who will provide comprehensive reimbursement support. They can help identify the patient's coverage and determine the patient's co-pay. Growth Solutions® will attempt to obtain prior authorization for treatment or assist with appeals if necessary. Additionally, Growth Solutions® will work to reduce the time involved in the benefits investigation process.

Q: How will I know whether my patient's insurance coverage has been approved?

A: Growth Solutions® will send an update via fax to the physician's office. This fax will identify the current stage of the investigation process. An additional fax will be sent to notify the office when a start date has been obtained.

Q: What happens if a patient lacks sufficient insurance coverage and cannot afford therapy?

A: Growth Solutions® has Benefits Investigation Specialists who will help identify alternate forms of assistance that may be available to qualifying patients who cannot afford therapy.

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Common Questions About Growth Solutions®

Home Training

Q: How do the home training appointments work?

A: Home training is a free benefit of Growth Solutions®.

Growth Solutions® will arrange to have a nurse educator train pediatric patients and their caregivers to properly deliver TEV-TROPIN® with a needle and syringe.

The nurse will guide them step-by-step through reconstitution and injection administration.

The physician or office staff may choose to handle their own patient-administration training. The Growth Solutions® home training program is a helpful option for busy practitioners, staff, and patients.

TEV-TROPIN® is indicated only for the treatment of children who have growth failure due to inadequate secretion of normal endogenous growth hormone (GH).

Important Safety Information

TEV-TROPIN® stimulates linear growth in children lacking endogenous GH. Treatment of growth hormone-deficient (GHD) children with TEV-TROPIN® produces growth rate and IGF-1 levels similar to those seen after treatment with hGH of pituitary origin.

Unless patients with Prader-Willi Syndrome (PWS) also have a diagnosis of GHD, TEV-TROPIN® is not indicated for treatment of pediatric patients who have growth failure due to genetically confirmed PWS. Because of reported fatalities, patients with PWS who are severely obese, have severe respiratory impairment, respiratory infections, or sleep apnea should interrupt use of GH.

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Important Safety Information (continued)

Patients should be observed for evidence of glucose intolerance, hypopituitarism, malignant transformation of skin lesions, hypothyroidism, slipped capital femoral epiphysis, and intracranial hypertension. Funduscopic examination of patients is recommended at the initiation and periodically during the course of GH treatment. TEV-TROPIN® should not be initiated in patients with acute critical illness as a complication of open heart surgery, abdominal surgery, multiple accidental trauma, or those with acute respiratory failure. TEV-TROPIN® should not be used in patients with evidence of an active malignancy, progressive or recurrent underlying intracranial tumor, active proliferative or severe nonproliferative diabetic retinopathy, or closed epiphysis.

When somatropin is administered subcutaneously at the same site over a long period of time, tissue atrophy may result. This can be avoided by rotating the injection site.

Because somatropin increases growth rate, patients with a history of scoliosis who are treated with somatropin should be monitored for progression of scoliosis.

Somatropin may alter the clearance of drugs metabolized by the CP450 enzyme system and careful monitoring is advisable.

Benzyl alcohol associated with toxicity in newborns is contained in the diluent supplied with TEV-TROPIN®. Treatment of patients with coexisting ACTH deficiency should have glucocorticoid replacement dose adjusted to avoid inhibition of growth.

In studies of growth hormone-deficient children, headaches occurred infrequently. Injection-site reactions (eg, pain, bruise) occurred in 8 of the 164 treated patients.

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TEV-TROPIN®

℞ only

[somatropin (rDNA origin) for injection]
5 mg (15 IU)

DESCRIPTION

TEV-TROPIN® (somatropin, rDNA origin, for injection), a polypeptide of recombinant DNA origin, has 191 amino acid residues and a molecular weight of about 22,124 daltons. It has an amino acid sequence identical to that of human growth hormone of pituitary origin. TEV-TROPIN® is synthesized in a strain of *Escherichia coli* modified by insertion of the human growth hormone gene.

TEV-TROPIN® is a sterile, white, lyophilized powder, intended for subcutaneous administration, after reconstitution with bacteriostatic 0.9% sodium chloride injection, USP, (normal saline) (benzyl alcohol preserved). The quantitative composition of the lyophilized drug per vial is:

5 mg (15 IU) vial:

Somatropin	5 mg (15 IU)
Mannitol	30 mg

The diluent contains bacteriostatic 0.9% sodium chloride injection, USP, (normal saline), 0.9% benzyl alcohol as a preservative, and water for injection. A 5 mL vial of the diluent will be supplied with each dispensed vial of TEV-TROPIN®.

TEV-TROPIN® is a highly-purified preparation. Reconstituted solutions have a pH in the range of 7.0 to 9.0.

CLINICAL PHARMACOLOGY

Clinical trials have demonstrated that TEV-TROPIN® is equivalent in its therapeutic effectiveness and in its pharmacokinetic profile to those of human growth hormone of pituitary origin (somatropin). TEV-TROPIN® stimulates linear growth in children who lack adequate levels of endogenous growth hormone. Treatment of growth hormone-deficient children with TEV-TROPIN® produces increased growth rates and IGF-1 (Insulin-Like Growth Factor/Somatomedin-C) concentrations that are similar to those seen after therapy with human growth hormone of pituitary origin.

Both TEV-TROPIN® and somatropin have also been shown to have other actions including:

A. Tissue Growth

1. Skeletal Growth. TEV-TROPIN® stimulates skeletal growth in patients with growth hormone deficiency. The measurable increase in body length after administration of TEV-TROPIN® results from its effect on the epiphyseal growth plates of long bones. Concentrations of IGF-1, which may play a role in skeletal growth, are low in the serum of growth hormone-deficient children but increase during treatment with TEV-TROPIN®. Mean serum alkaline phosphatase concentrations are increased.
2. Cell Growth. It has been shown that there are fewer skeletal muscle cells in short statured children who lack endogenous growth hormone as compared with normal children. Treatment with somatropin results in an increase in both the number and size of muscle cells.
3. Organ Growth. Somatropin influences the size of internal organs and it also increases red cell mass.

B. Protein Metabolism

Linear growth is facilitated, in part, by increased cellular protein synthesis. Nitrogen retention, as demonstrated by decreased urinary nitrogen excretion and serum urea nitrogen, results from treatment with somatropin.

C. Carbohydrate Metabolism

Children with hypopituitarism sometimes experience fasting hypoglycemia that is improved by treatment with somatropin. Large doses of somatropin may impair glucose tolerance.

D. Lipid Metabolism

Administration of somatropin to growth hormone-deficient patients mobilizes lipid, reduces body fat stores, and increases plasma fatty acids.

E. Mineral Metabolism

Sodium, potassium, and phosphorous are conserved by somatropin. Serum concentrations of inorganic phosphates increased in patients with growth hormone deficiency after therapy with TEV-TROPIN® or somatropin. Serum calcium concentrations are not significantly altered in patients treated with either somatropin or TEV-TROPIN®.

F. Connective Tissue Metabolism

Somatropin stimulates the synthesis of chondroitin sulfate and collagen as well as the urinary excretion of hydroxyproline.

PHARMACOKINETICS

Following intravenous administration of 0.1 mg/kg of TEV-TROPIN®, the elimination half-life was about 0.42 hours (approximately 25 minutes) and the mean plasma clearance (± SD) was 133 (± 16) mL/min in healthy male volunteers.

In the same volunteers, after a subcutaneous injection of 0.1 mg/kg TEV-TROPIN® to the forearm, the mean peak serum concentration (± SD) was 80 (± 50) ng/mL which occurred approximately 7 hours post-injection and the apparent elimination half-life was approximately 2.7 hours. Compared to intravenous administration, the extent of systemic availability from subcutaneous administration was approximately 70%.

INDICATION AND USAGE

TEV-TROPIN® is indicated only for the treatment of children who have growth failure due to an inadequate secretion of normal endogenous growth hormone.

CONTRAINDICATIONS

TEV-TROPIN® reconstituted with bacteriostatic 0.9% sodium chloride injection, USP (normal saline) (benzyl alcohol preserved) should not be administered to patients with a known sensitivity to benzyl alcohol (see **WARNINGS**).

Somatropin should not be used for growth promotion in pediatric patients with closed epiphyses.

Somatropin is contraindicated in patients with active proliferative or severe non-proliferative diabetic retinopathy.

In general, somatropin is contraindicated in the presence of active malignancy. Any preexisting malignancy should be inactive and its treatment complete prior to instituting therapy with somatropin. Somatropin should be discontinued if there is evidence of recurrent activity. Since growth hormone deficiency may be an early sign of the presence of a pituitary tumor (or, rarely, other brain tumors), the presence of such tumors should be ruled out prior to initiation of treatment. Somatropin should not be used in patients with any evidence of progression or recurrence of an underlying intracranial tumor.

Somatropin should not be used to treat patients with acute critical illness due to complications following open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure. Two placebo-controlled clinical trials in non-growth hormone deficient adult patients (n = 522) with these conditions in intensive care units revealed a significant increase in mortality (41.9% vs. 19.3%) among somatropin-treated patients (doses 5.3 to 8 mg/day) compared to those receiving placebo (see **WARNINGS**).

Somatropin is contraindicated in patients with Prader-Willi syndrome who are severely obese or have severe respiratory impairment (see **WARNINGS**). Unless patients with Prader-Willi syndrome also have a diagnosis of growth hormone deficiency, TEV-TROPIN® is not indicated for the treatment of pediatric patients who have growth failure due to genetically confirmed Prader-Willi syndrome.

WARNINGS

See **CONTRAINDICATIONS** for information on increased mortality in patients with acute critical illnesses due to complications following open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure. The safety of continuing somatropin treatment in patients receiving replacement doses for approved indications who concurrently develop these illnesses has not been established. Therefore, the potential benefit of treatment continuation with somatropin in patients having acute critical illnesses should be weighed against the potential risk.

There have been reports of fatalities after initiating therapy with somatropin in pediatric patients with Prader-Willi syndrome who had one or more of the following risk factors: severe obesity, history of upper airway obstructions or sleep apnea, or unidentified respiratory infection. Male patients with one or more of these factors may be at greater risk than females. Patients with Prader-Willi syndrome should be evaluated for signs of upper airway obstruction and sleep apnea before initiation of treatment with somatropin. If during treatment with somatropin, patients show signs of upper airway obstruction (including onset of or increased snoring) and/or new onset sleep apnea, treatment should be interrupted. All patients with Prader-Willi syndrome treated with somatropin should also have effective weight control and be monitored for signs of respiratory infection, which should be diagnosed as early as possible and treated aggressively (see **CONTRAINDICATIONS**).

Unless patients with Prader-Willi syndrome also have a diagnosis of growth hormone deficiency, TEV-TROPIN® is not indicated for the treatment of pediatric patients who have growth failure due to genetically confirmed Prader-Willi syndrome.

Benzyl alcohol as a preservative in bacteriostatic normal saline, USP, has been associated with toxicity in newborns. When administering TEV-TROPIN® to newborns, reconstitute with sterile normal saline for injection, USP. WHEN RECONSTITUTING WITH STERILE NORMAL SALINE, USE ONLY ONE DOSE PER VIAL AND DISCARD THE UNUSED PORTION.

PRECAUTIONS

General

Therapy with TEV-TROPIN® should be directed by physicians who are experienced in the diagnosis and management of children with growth hormone deficiency.

Treatment with somatropin may decrease insulin sensitivity, particularly at higher doses in susceptible patients. As a result, previously undiagnosed impaired glucose tolerance and overt diabetes mellitus may be unmasked during somatropin treatment. Therefore, glucose levels should be monitored periodically in all patients treated with somatropin, especially in those with risk factors for diabetes mellitus, such as obesity (including obese patients with Prader-Willi syndrome), Turner syndrome, or a family history of diabetes mellitus. Patients with preexisting type 1 or type 2 diabetes mellitus or impaired glucose tolerance should be monitored closely during somatropin therapy. The doses of antihyperglycemic drugs (i.e., insulin or oral agents) may require adjustment when somatropin therapy is instituted in these patients.

Patients with preexisting tumors or growth hormone deficiency secondary to an intracranial lesion should be examined routinely for progression or recurrence of the underlying disease process. In pediatric patients, clinical literature has revealed no relationship between somatropin replacement therapy and central nervous system (CNS) tumor recurrence or new extracranial tumors. However, in childhood cancer survivors, an increased risk of a second neoplasm has been reported in patients treated with somatropin after their first neoplasm. Intracranial tumors, in particular meningiomas, in patients treated with radiation to the head for their first neoplasm, were the most common of these second neoplasms. In adults, it is unknown whether there is any relationship between somatropin replacement therapy and CNS tumor recurrence.

Intracranial hypertension (IH) with papilledema, visual changes, headache, nausea, and/or vomiting has been reported in a small number of patients treated with somatropin products. Symptoms usually occurred within the first eight (8) weeks after the initiation of somatropin therapy. In all reported cases, IH-associated signs and symptoms rapidly resolved after cessation of therapy or a reduction of the somatropin dose. Funduscopic examination should be performed routinely before initiating treatment with somatropin to exclude preexisting papilledema, and periodically during the course of somatropin therapy. If papilledema is observed by funduscopy during somatropin treatment, treatment should be stopped. If somatropin-induced IH is diagnosed, treatment with somatropin can be restarted at a lower dose after IH-associated signs and symptoms have resolved. Patients with Turner syndrome, chronic renal insufficiency, and Prader-Willi syndrome may be at increased risk for the development of IH.

In patients with hypopituitarism (multiple hormone deficiencies), standard hormonal replacement therapy should be monitored closely when somatropin therapy is administered.

Undiagnosed/untreated hypothyroidism may prevent an optimal response to somatropin, in particular, the growth response in children. Patients with Turner syndrome have an inherently increased risk of developing autoimmune thyroid disease and primary hypothyroidism. In patients with growth hormone deficiency, central (secondary) hypothyroidism may first become evident or worsen during somatropin treatment. Therefore, patients treated with somatropin should have periodic thyroid function tests and thyroid hormone replacement therapy should be initiated or appropriately adjusted when indicated.

Patients should be monitored carefully for any malignant transformation of skin lesions.

When somatropin is administered subcutaneously at the same site over a long period of time, tissue atrophy may result. This can be avoided by rotating the injection site.

As with any protein, local or systemic allergic reactions may occur. Parents/patients should be informed that such reactions are possible and that prompt medical attention should be sought if allergic reactions occur.

Pediatric Patients (see PRECAUTIONS, General)

Slipped capital femoral epiphysis may occur more frequently in patients with endocrine disorders (including pediatric growth hormone deficiency and Turner syndrome) or in patients undergoing rapid growth. Any pediatric patient with the onset of a limp or complaints of hip or knee pain during somatropin therapy should be carefully evaluated.

Progression of scoliosis can occur in patients who experience rapid growth. Because somatropin increases growth rate, patients with a history of scoliosis who are treated with somatropin should be monitored for progression of scoliosis. However, somatropin has not been shown to increase the occurrence of scoliosis. Skeletal abnormalities including scoliosis are commonly seen in untreated Turner syndrome patients. Scoliosis is also commonly seen in untreated patients with Prader-Willi syndrome. Physicians should be alert to these abnormalities, which may manifest during somatropin therapy.

Information for Patients

Patients being treated with TEV-TROPIN® (and/or their parents) should be informed about the potential benefits and risks associated with TEV-TROPIN® treatment. This information is intended to better educate patients (and caregivers); it is not a disclosure of all possible adverse or intended effects.

Patients and caregivers who will administer TEV-TROPIN® should receive appropriate training and instruction on the proper use of TEV-TROPIN® from the physician or other suitably qualified health care professional. A puncture-resistant container for the disposal of used syringes and needles should be strongly recommended. Patients and/or parents should be thoroughly instructed in the importance of proper disposal, and cautioned against any reuse of needles and syringes. This information is intended to aid in the safe and effective administration of the medication.

Laboratory Tests

Serum levels of inorganic phosphorus, alkaline phosphatase, parathyroid hormone (PTH) and IGF-1 may increase during somatropin therapy.

Drug Interactions

Somatropin inhibits 11ß-hydroxysteroid dehydrogenase type 1 (11ßHSD-1) in adipose/hepatic tissue and may significantly impact the metabolism of cortisol and cortisone. As a consequence, in patients treated with somatropin, previously undiagnosed central (secondary) hypoadrenalism may be unmasked requiring glucocorticoid replacement therapy. In addition, patients treated with glucocorticoid replacement therapy for previously diagnosed hypoadrenalism may require an increase in their maintenance or stress doses; this may be especially true for patients treated with cortisone acetate and prednisone since conversion of these drugs to their biologically active metabolites is dependent on the activity of the 11ßHSD-1 enzyme.

Excessive glucocorticoid therapy may attenuate the growth promoting effects of somatropin in children. Therefore, glucocorticoid replacement therapy should be carefully adjusted in children with concomitant GH and glucocorticoid deficiency to avoid both hypoadrenalism and an inhibitory effect on growth.

Limited published data indicate that somatropin treatment increases cytochrome P450 (CP450) mediated antipyrine clearance in man. These data suggest that somatropin administration may alter the clearance of compounds known to be metabolized by CP450 liver enzymes (e.g., corticosteroids, sex steroids, anticonvulsants, cyclosporine). Careful monitoring is advisable when somatropin is administered in combination with other drugs known to be metabolized by CP450 liver enzymes. However, formal drug interaction studies have not been conducted.

In patients with diabetes mellitus requiring drug therapy, the dose of insulin and/or oral agent may require adjustment when somatropin therapy is initiated (see **PRECAUTIONS**, **General**).

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis, mutagenesis and reproduction studies have not been conducted with TEV-TROPIN®.

Pregnancy

Pregnancy Category C

Animal reproduction studies have not been conducted with TEV-TROPIN®. It is not known whether TEV-TROPIN® can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. TEV-TROPIN® should be given to a pregnant woman only if clearly needed.

Nursing Mothers

There have been no studies conducted with TEV-TROPIN® in nursing mothers. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when TEV-TROPIN® is administered to a nursing woman.

Geriatric Use

The safety and effectiveness of TEV-TROPIN® in patients aged 65 and over has not been evaluated in clinical studies. Elderly patients may be more sensitive to the action of somatropin, and therefore may be more prone to develop adverse reactions. A lower starting dose and smaller dose increments should be considered for older patients.

ADVERSE REACTIONS

Utilizing a double-antibody immunoassay, no antibodies to growth hormone could be detected in a group of 164 naïve and previously treated clinical trial patients after treatment with TEV-TROPIN® for up to 40 months. However, utilizing the less specific polyethelene glycol (PEG) precipitation immunoassay, 27 of the 164 patient group were tested after treatment with TEV-TROPIN® for 4 to 6 months and antibodies to growth hormone were detected in two patients (7.4%). The binding capacity of the antibodies from the two antibody positive patients was not determined.

None of the patients with anti-GH antibodies in the clinical studies experienced decreased linear growth response to TEV-TROPIN® or any other associated adverse event. Growth hormone antibody binding capacities below 2 mg/L have not been associated with growth attenuation. In some cases, when binding capacity exceeds 2 mg/L, growth attenuation has been observed.

In studies of growth hormone-deficient children, headaches occurred infrequently. Injection site reactions (e.g., pain, bruise) occurred in 8 of the 164 treated patients.

Leukemia has been reported in a small number of patients treated with other growth hormone products. It is uncertain whether this risk is related to the pathology of growth hormone deficiency itself, growth hormone therapy, or other associated treatments such as radiation therapy for intracranial tumors.

OVERDOSAGE

The recommended dosage of up to 0.1 mg/kg (0.3 IU/kg) of body weight 3 times per week should not be exceeded. Acute overdose could cause initial hypoglycemia and subsequent hyperglycemia. Repeated use of doses in excess of those recommended could result in signs and symptoms of gigantism and/or acromegaly consistent with the known effects of excess human growth hormone.

DOSAGE AND ADMINISTRATION

A dosage of up to 0.1 mg/kg (0.3 IU/kg) of body weight administered 3 times per week by subcutaneous injection is recommended. The dosage schedule for TEV-TROPIN® should be individualized for each patient. Subcutaneous injection of greater than 1 mL of reconstituted solution is not recommended.

After the dose has been determined, each vial of TEV-TROPIN® should be reconstituted with 1 to 5 mL of bacteriostatic 0.9% sodium chloride for injection, USP (benzyl alcohol preserved).*

The stream of normal saline should be aimed against the side of the vial to prevent foaming. Swirl the vial with a GENTLE rotary motion until the contents are completely dissolved and the solution is clear. DO NOT SHAKE. Since TEV-TROPIN® is a protein, shaking or vigorous mixing will cause the solution to be cloudy. If the resulting solution is cloudy or contains particulate matter, the contents MUST NOT be injected.

* Benzyl alcohol as a preservative in bacteriostatic normal saline, USP, has been associated with toxicity in newborns. When administering TEV-TROPIN® to newborns, reconstitute with sterile normal saline for injection, USP.

Occasionally, after refrigeration, some cloudiness may occur. This is not unusual for proteins like TEV-TROPIN® growth hormone. Allow the product to warm to room temperature. If cloudiness persists or particulate matter is noted, the contents MUST NOT be used.

Before and after injection, the septum of the vial should be wiped with rubbing alcohol or an alcoholic antiseptic solution to prevent contamination of the contents by repeated needle insertions. It is recommended that TEV-TROPIN® be administered using sterile disposable syringes and needles. The syringes should be of small enough volume that the prescribed dose can be drawn from the vial with reasonable accuracy.

STABILITY AND STORAGE

Before Reconstitution – Vials of TEV-TROPIN® are stable when refrigerated at 36° to 46°F (2° to 8°C). Expiration dates are stated on the labels.

After Reconstitution – Vials of TEV-TROPIN® are stable for up to 14 days when reconstituted with bacteriostatic 0.9% sodium chloride (normal saline), USP, and stored in a refrigerator at 36° to 46°F (2° to 8°C). Do not freeze the reconstituted solution.

HOW SUPPLIED

TEV-TROPIN® (somatropin, rDNA origin, for injection) is supplied as 5 mg (15 IU) of lyophilized, sterile somatropin per vial, in a box containing one vial of TEV-TROPIN® (5 mg per vial) and one vial of diluent [5 mL of bacteriostatic 0.9% sodium chloride for injection, USP (benzyl alcohol preserved)].

Manufactured In Israel By:
BIO-TECHNOLOGY GENERAL (ISRAEL) LTD.
Be'er Tuvia, Israel
Distributed By:
GATE PHARMACEUTICALS
div. of Teva Pharmaceuticals USA Rev. J 10/2007
Sellersville, PA 18960 0082-5008v5

Growth Solutions

A comprehensive services program for you and your patients

- Reimbursement support for those patients who need it
- Training and assistance to help educate patients and their caregivers

Call 866-TEV-TROP (866-838-8767)
Fax 877-TEV-TROP (877-838-8767)
or visit www.tev-tropin.com

Please see full prescribing information at the back of this guide.

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